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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,512	04/16/2004	Jian Cao	P-10368.00	1952
27581	7590	12/05/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			BERTRAM, ERIC D	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/826,512

Applicant(s)

CAO ET AL.

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 9/21/06 have been fully considered but they are not persuasive. The Applicant argues that Kim does not teach determining whether there are consecutive beats having first characteristics and identifying a predetermined number of events subsequent to the consecutive events having second characteristics as first selected events, and generating the template from only the first selected events. The Examiner respectfully disagrees. In paragraphs 0068-0071, Kim discloses initiating a template update by sensing signals from the heart. Initially, 20 consecutive RR intervals are sensed in order to determine if the average of the RR intervals (first characteristics) of these 20 first consecutive events surpasses a threshold. Template generation is then continued, and as the sensing continues (see par. 0074), beats that occur subsequent to the first consecutive events may be classified as NSR beats if they have the second characteristics described in paragraph 0078. These NSR beats are classified as first selected events. Kim further discloses that only the NSR beats are used as template beats in order to generate a new template (par. 0081-0083).
2. The applicant further argues that a "cross-match" as disclosed by Kim does not correspond to cross-matching as described in the present application. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that a cross-match is computed by matching one non-paced beat against another non-paced beat of the predetermined number of non-paced beats) are not recited in the rejected claim(s).

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Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The broadest reasonable interpretation of a "cross-match" is to compare two objects to determine if they are substantially the same. Given this broadest reasonable interpretation of a cross-match, Kim discloses that the predetermined number of events are cross-matched using a feature correlation coefficient (FCC), such that if 10 out of 21 first selected events have a FCC greater than 0.95, then they are sufficiently similar to replace the currently stored template (see par. 0108).

3. As a result, the 35 USC 102(b) rejections of claims 1, 2, 5-8, 11-13, 16, 17, 20-22, 25-28, 31 and 32 are still considered proper. Furthermore, since the arguments against Kim were solely relied upon to overcome the 35 USC 103(a) rejections of claims 3, 4, 9, 10, 14, 15, 18, 19, 23, 24, 29, 30, 33 and 34 are also still considered proper.

#### ***Specification***

4. The amendments to the specification are acknowledged and accepted. As a result, the objection to the specification has been withdrawn.

#### ***Claim Objections***

5. The amendments to the claims are acknowledged and accepted. As a result, the objection to the claims has been withdrawn.

#### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-6, 11, 12, 27-30 and 31-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 20-23 of copending Application No. 10/826618. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application contain all of the limitations of the current application in addition to other limitations.

8. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 1, 2, 5-8, 11-13, 16, 17, 20-22, 25-28, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (US 2002/0183637, hereinafter Kim).

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Kim discloses a device/method for generating a template in an implantable medical device. Kim describes sensing a plurality of events from sensed rate channels, then determining whether these consecutive events have first characteristics. Specifically, after sensing the first consecutive events, if the average RR interval is greater than a threshold interval, then the template generation continues (par. 0068-0071). Following this process, a plurality of events subsequent to the first consecutive events, having second characteristics, are identified as first selected events if they surpass a threshold, and a template can be generated based on these selected events (par. 0081-0083).

11. Regarding claims 5, 6 and 25, cross-matches are determined between the events identified as first selected events, a predetermined number is established, and the template is generated from this group of super-threshold, predetermined number of events (par. 0108). Furthermore, a delay is generated if the predetermined number of events fails to generate a predetermined number of cross-matches (par. 0108).

12. Regarding claims 7, 8, 12 and 13, if the predetermined number of events does not surpass a cross-match threshold, then a plurality of events similar having the second characteristics will be used to generate a new template (par. 0087).

13. Regarding claim 11, R-R intervals associated with the first events are compared to an average (par. 0071), a cross-match is computed (par. 0105) if the R-R intervals are greater than the average, and a template is generated from the events corresponding to the cross-matches (par. 0108).

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14. Regarding claims 16, 17, 20 and 26, Kim discloses that the template update operation can be repeated indefinitely every 10 minutes to 24 hours (par. 0064), and the repetition can be based on whether or not the threshold value is reached (par. 0108).

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



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18. Claims 3, 4, 9, 10, 14, 15, 18, 19, 23, 24, 29, 30, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim. Kim discloses the essential features of the claimed invention including a sense event that is not a ventricular pace event (par. 0067) and an event having an R-R interval greater than a predetermined rate of about 600 ms (par. 0071). Kim does not disclose that sense events can comprise events other than those directly following a ventricular pace and sense events preceded by atrial paces by more than a threshold value. It is well known in the art that sensed events during or directly following an arrhythmia therapy are not representative of the natural electrical activity of the heart and should not be used as measurements representative of the natural electrical activity. Additionally, Kim discloses excluding senses related to therapy application (par. 0067) and within a pacing threshold (par. 0081) to exclude beats that are not representative of the natural electrical activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim's invention by excluding events following a ventricular pace and sense events preceded by an atrial pace by less than a threshold duration of time to exclude beats that are not representative of the natural electrical activity of the heart.

19. Regarding claims 4, 10, 15, 19, 24, 30 and 34, the modified invention of Kim discloses the claimed invention, but does not disclose expressly the AV threshold interval of 100 ms. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Kim with the threshold interval of 100 ms because applicant has not disclosed that 100 ms provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art,

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furthermore, would have expected applicant's invention to perform equally well with the method as taught by Kim because Kim's invention excludes sense events related to arrhythmia therapy, thus excluding sensed events that are not representative of the natural electrical activity of the heart. Therefore, it would have been an obvious matter of design choice to modify Kim's invention by using an AV threshold interval of 100 ms to obtain the invention as specified in the claims.

### ***Conclusion***

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram  
Examiner  
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EDB



Robert E. Pezzuto  
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